

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL**  
FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER:

04-01

2. STATE:

Maryland

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL  
SECURITY ACT (MEDICAID) MedicaidTO: REGIONAL ADMINISTRATOR  
HEALTH CARE FINANCING ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

July 1, 2003

5. TYPE OF PLAN MATERIAL (Check One):

☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

See attached

7. FEDERAL BUDGET IMPACT:

a. FFY 2004 \$ [8M]

b. FFY \$

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1A page 27-A-1 (04-01)

Attachment 3.1A page 27-A-2

Attachment 3.1A, page 27-A-3

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable):

Attachment 3.1A page 27-A-1 (03-07)

10. SUBJECT OF AMENDMENT:

Amendments to implement the new preferred drug list program.

11. GOVERNOR'S REVIEW (Check One):

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL☒ OTHER, AS SPECIFIED:Susan J. Tucker, Executive Director  
Office of Health Services

12. SIGNATURE OF STATE AGENCY OFFICIAL:

Nelson J. Sabatini

13. TYPED NAME:

Nelson J. Sabatini

14. TITLE:

Secretary

15. DATE SUBMITTED:

7/22/03

16. RETURN TO:

Susan J. Tucker, Executive Director  
OHS-DHMH  
201 W. Preston St., Ste 124  
Baltimore, MD 212 01

## FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

JULY 30, 2003

18. DATE APPROVED:

OCT 22, 2003

## PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

JULY 1, 2003

20. SIGNATURE OF REGIONAL OFFICIAL:

Mary T. McSorley

21. TYPED NAME:

Mary T. McSorley

22. TITLE: Associate Regional Administrator  
Division of Medicaid & Children's Health

23. REMARKS:

STATE PLAN OF MEDICAL ASSISTANCE  
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT  
STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A Prescribed Drugs	<p>6. Nursing home prescriptions</p> <p>(a) Claims shall be identified as nursing home prescriptions by coding mechanisms determined by the Program;</p> <p>(b) Credits, less the paid dispensing fee, for unused unit dose medication and any other medication which may legally be returned to stock shall be made within 60 days of Program payment and include adjustments for leave of absence prescriptions; and</p> <p>(c) Multiple prescriptions dispensed to a recipient residing in a nursing home for the same drug product or compounded prescription shall receive only one professional fee per calendar month except for:</p> <p>(i) Leave of absence prescription,</p> <p>(ii) Compounded prescriptions for home intravenous therapy, and</p> <p>(iii) Prescriptions for Schedule II-IV controlled dangerous substances.</p> <p>7. Preauthorization is not required for:</p> <p>(a) Prescriptions for oral contraceptive drug products;</p> <p>(b) Drugs dispensed in unit dose form to patients in a nursing facility by a provider using an approved unit dose system.</p>

TN# 04-01  
Supersedes TN# 03-07

Approval Date OCT. 22, 2003  
Effective Date July 1, 2003

STATE PLAN OF MEDICAL ASSISTANCE  
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT  
STATE OF MARYLAND

PROGRAM

LIMITATIONS

Continued  
12.A. Prescribed  
drugs

8. (a) The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

(b) The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

(c) A rebate agreement between the state and a drug manufacturer for drugs provided to Medicaid recipients, submitted to CMS on July 21, 2003 and entitled "State of Maryland Department of Health and Mental Hygiene Supplemental Rebate Agreement" has been authorized by CMS.

(d) Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

(e) All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.

TN# 04-01  
Supersedes TN# 03-07

Approval Date OCT 22, 2003  
Effective Date JULY 1, 2003

STATE PLAN OF MEDICAL ASSISTANCE  
UNDER TITLE XIX OF THE SOCIAL SECURITY ACT  
STATE OF MARYLAND

PROGRAM	LIMITATIONS
Continued 12.A. Prescribed drugs	(f) The state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list pursuant to 42 U.S.C. section 1396r-8. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.  (g) Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses in compliance with federal law.  (h) The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.
12. B. Dentures See "Limitations" Item 10, "Dental Services"	

TN# 04-01  
Supersedes TN# 03-07

Approval Date OCT. 22, 2003  
Effective Date JULY 1, 2003

**State of Maryland**  
**Department of Health and Mental Hygiene**  
**Supplemental Rebate Agreement**

The State of Maryland acting by and through the Maryland Department of Health and Mental Hygiene, 201 W. Preston Street, Baltimore, Maryland 21201(hereinafter collectively referred to as "Department"), and [Manufacturer] (hereinafter referred to as "Manufacturer"), hereby enter into the following Supplemental Rebate Agreement.

**WHEREAS**, the Department administers the Maryland Medicaid Program under Title XIX of the Social Security Act (42 U.S.C. 1396 *et seq.*); and

**WHEREAS**, the Department is authorized to enter into supplemental rebate agreements pursuant to Maryland Code Ann., Health-Gen. § 15-103 and the Code of Maryland Regulations (COMAR) 10.09.03.12.

**WHEREAS**, the Department and the Manufacturer desire to provide for supplemental rebates on certain of Manufacturer's pharmaceutical products dispensed to Medicaid recipients and reimbursed by the Department;

**NOW THEREFORE**, in consideration of the mutual promises and covenants contained herein, the parties agree as follows:

**Article 1. Definitions.** As used in this Agreement, the following terms have the following meanings:

- 1.1. "Average Manufacturer Price" or "AMP" shall mean, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.
- 1.2. "Best Price" shall mean Best Price as set forth in 42 U.S.C. §1396r-8, as such may be amended from time to time, excluding State Supplemental Rebate amounts.
- 1.3. "CMS" shall mean the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the United States Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.
- 1.4. "Fiscal Quarter" shall mean one of the four three-month periods by which the fiscal year is divided, that fiscal year beginning July 1 and ending on the following June 30.

- 1.16 "Wholesale Acquisition Price" or "WAC" shall mean the Direct Manufacturer Price Wholesale Unit Price (BB\_P) as of the first day of a Fiscal Quarter published in the National Drug Data File by First Data Bank, Inc.

## **Article 2. Term and Scope of Agreement.**

- 2.1. Term. The term of this Agreement shall be from October 1, 2003, through September 30, 2004, unless the Agreement is otherwise terminated as set forth herein.
- 2.2. Entirety of Agreement. The terms and conditions of this Agreement along with applicable Departmental Administrative Regulations and any documents expressly incorporated herein shall constitute the entire present agreement between the parties. This Agreement constitutes a total integration of all rights, benefits and obligations of the parties, and there exist no other agreements or understandings, oral or otherwise, that bind any of the parties regarding the subject matter of this Agreement.

## **Article 3. Termination.**

- 3.1. Termination Without Cause. Notwithstanding any contrary provision in this Agreement, the Agreement may be terminated at the option of either party upon sixty (60) days written notice to the other party.
- 3.2. Nonwaiver. Failure of either party to insist on performance of any term or condition of this Agreement or to exercise any right or privilege hereunder shall not be construed as a continuing or future waiver of such term, condition, right or privilege.
- 3.3. Violation of Law. Manufacturer may immediately terminate this Agreement if there is a determination by any court or any authorized governmental authority that the arrangements and transactions under this Agreement or any similar agreement constitute a violation of any law or regulation including without limitation 42 USC 1320a-7b(b) prohibiting illegal remuneration.
- 3.4. Bankruptcy and Insolvency. The Department shall have the right to cancel this Agreement immediately and without prior notice in the event Manufacturer is adjudicated bankrupt, makes an assignment for the benefit of creditors without the Department's prior written consent (which shall not be unreasonably withheld) or if a receiver is appointed for Manufacturer.
- 3.5. Effect on Accrued Obligations. Termination of this Agreement shall have no effect upon the rights and obligations of the parties arising out of any transaction occurring prior to the effective date of such termination.

## **Article 4. Agreement Management and Notices.**

- B. *Timeliness.* Manufacturer's failure to remit the State Supplemental Rebate amount in a timely manner may result in the removal of the relevant Product or Products from the Preferred Drug List, pursuant to the application of the dispute resolution process set forth in Paragraph D, below.
- C. *Incomplete Submission.* Manufacturer shall have no obligation for claims that are not submitted as part of an invoice in accordance with Section 6.4 of this Agreement. Manufacturer shall notify the Department or its designee of any incomplete submission within thirty-eight (38) days after Manufacturer's receipt of such submission. Manufacturer shall notify the Department or its designee of any incomplete submission within thirty-eight (38) days after Manufacturer's receipt of such submission pursuant to Section 6.4.
- D. *Over/Underpayment.* If either party discovers an error in the payment of State Supplemental Rebates by Manufacturer, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with generally applicable procedures followed by the Department or CMS in disputes concerning National Rebates. Manufacturer shall deduct any overpayment from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, the Department will refund any such overpayment to Manufacturer within thirty (30) days after its acknowledgment of the overpayment. Manufacturer will remit any underpayment to the Department within thirty (30) days after Manufacturer's acknowledgment of such underpayment. All other disputes will be resolved in accordance with generally applicable procedures followed by the Department and CMS in disputes concerning the Maryland Medicaid Program.
- E. *Product Utilization Eligible for Rebate.* Product utilization under the Preferred Drug List shall be eligible for State Supplemental Rebates pursuant to Attachment C only if and when it meets all of the following conditions:
  - 1. *Own Use.* The Product shall have been dispensed and used in connection with this Agreement only for Medicaid Recipients and only for their own use.
  - 2. *Late Submission.* Utilization information for such Product has been provided within one hundred eighty (180) days after the Fiscal Quarter in which the Product was paid for by the Department.
- F. *Partial Quarter Submissions.* In the event that a Product is placed on or removed from the Preferred Drug List after the beginning of a Fiscal Quarter, the State Supplemental Rebate for the Product for that Fiscal Quarter shall be calculated by multiplying the SRPU for that Quarter as set

shall provide Manufacturers the opportunity to provide information on the Product's merits for inclusion in the Preferred Drug List.

- D. *Addition of New Products to Preferred Drug List.* The Manufacturer shall notify the Department of any New Product and the State Supplemental Rebate available on such New Product. Provided that the price of such product, less any National Rebate or State Supplemental Rebate available on such New Product, is acceptable to the Department, the Department may, after review by the P&T Committee, add such New Product to this Agreement via a written amendment signed by both parties. The effective date of the State Supplemental Rebate for such New Product will be the date of its acceptance by the P&T Committee, unless otherwise agreed by the parties.
- 6.4. Invoicing. The Department shall invoice State Supplemental Rebates separately from National Rebates, using the format set forth in Attachment B. The Department shall submit the State Supplemental Rebate invoice to Manufacturer within ninety (90) days after the Fiscal Quarter in which the Product was paid for by the Department. Any amended invoice shall be submitted by the Department within twelve (12) months after the Fiscal Quarter in which the Product was paid for by the Department. The Department shall not provide to Manufacturer any patient identifiable information or protected health information or any other information the disclosure of which is prohibited or regulated by laws or regulations governing confidentiality of medical or other information.
- 6.5. Fraud & Abuse. It is the Department's belief that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 U.S.C. 1320a-7b(b) prohibiting illegal remuneration. Should the above provisions apply, it is the Department's belief that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. 1320a-7b(b)(3)(A), which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program. The Department currently provides CMS full and unfettered access to all information held by the Department regarding the implementation of the Maryland Medicaid Program, and shall continue to do so throughout the implementation of the State Supplemental Rebate and Preferred Drug List program.
- 6.6. CMS Approval. The Department represents and warrants that CMS has approved this Agreement and found that the payment of Supplemental Rebates hereunder shall not affect Manufacturer's calculation of Best Price or AMP.

## **Article 7. General Terms.**

- 7.1. Agreement to Obey All Laws. Manufacturer shall at all times observe, comply with, and perform all obligations hereunder in accordance with, all laws, ordinances,

be due to the Department/Manufacturer. *Retention of Records.* Manufacturer shall maintain all business, professional, and other records in accordance with State law, 45 CFR Part 74, the specific terms and conditions of this Agreement, and pursuant to generally accepted accounting practice. Manufacturer shall maintain, during the pendency of the Agreement and for a minimum of three (3) years after the completion of the Agreement, adequate books, records, and supporting documents to verify the amounts, recipients, and uses of all disbursements of funds passing in conjunction with the Agreement. If an audit, litigation, or other action involving the records is begun before the end of the three-year period, the records must be retained until all issues arising out of the action are resolved. Failure to maintain the books, records, and supporting documents required by this Article shall establish a presumption in favor of the Department for the recovery of any funds paid by the Department under the Agreement for which adequate books, records, and other documents are not available to support the purported disbursement.

7.5. Choice of Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland. The State shall not enter binding arbitration to resolve any Agreement dispute. The State of Maryland does not waive sovereign immunity by entering into this Agreement.

7.6. Confidentiality.

A. *Proprietary Information.* Subject to 42 U.S.C. § 1396r-8(b)(3)(D) and subject to any other applicable state and federal law, performance of the Agreement may require Manufacturer to have access to and use of documents and data which may be confidential or considered proprietary to the State or to a State contractor, or which may otherwise be of such a nature that its dissemination or use, other than in performance of the Agreement, would be adverse to the interest of the State or others. Any documents or data obtained by Manufacturer from the Department in connection with carrying out the services under this Agreement shall be kept confidential and not provided to any third party unless disclosure is approved in writing by the Department. Each party shall protect the confidentiality of information provided by the other party, or to which the receiving party obtains access by virtue of its performance under this Agreement, that either has been reasonably identified as confidential by the disclosing party or by its nature warrants confidential treatment. The receiving party shall use such information only for the purpose of this Agreement and shall not disclose it to anyone except those of its employees who need to know the information. These nondisclosure obligations shall not apply to information that is or becomes public through no breach of this Agreement, that Agreement that is received from a third party free to disclose it, that is independently developed by the receiving party, or that is required by law to be disclosed. Confidential information shall be returned to the disclosing party upon request. In addition, the Department agrees this Agreement and any information

employ any person or persons employed by the Department at any time during the term of this Agreement for any work required by the terms of this Agreement.

- 7.12. Rules of Construction. Unless the context otherwise requires or unless otherwise specified, the following rules of construction apply to this Agreement:
- A. Provisions apply to successive events and transactions;
  - B. "Or" is not exclusive;
  - C. References to statutes and rules include subsequent amendments and successors thereto;
  - D. The various headings of this Agreement are provided for convenience only and shall not affect the meaning or interpretation of this Agreement or any provision hereof;
  - E. If any payment or delivery hereunder shall be due on any day which is not a business day, such payment or delivery shall be made on the next succeeding business day;
  - F. "Days" shall mean calendar days; "; "business day" shall mean a weekday (Monday through Friday), excepting State holidays, between the hours of 8:00 a.m. Eastern Time and 4:00 p.m. Eastern Time;
  - G. Use of the male gender (e.g., "he", "him", "his") shall be construed to include the female gender (e.g., "she", "her"), and vice versa; and
  - H. Words in the plural which should be singular by context shall be so read, and vice versa.
- 7.13. Sale or Transfer. Manufacturer shall provide the Department with the earliest commercially reasonable advance notice of any sale or transfer of Manufacturer's business. The Department has the right to terminate this Agreement without cause upon notification of such sale or transfer.
- 7.14. Severability. In the event that any provision, term or condition of this Agreement is declared void, unenforceable, or against public policy, then said provision, term or condition shall be construed as though it did not exist and shall not affect the remaining provisions, terms, or conditions of this Agreement, and this Agreement shall be interpreted as far as possible to give effect to the parties' intent.
- 7.15. Survival of Obligations. Those obligations under this Agreement which by their nature are intended to continue beyond the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement.

**ATTACHMENT A**  
**COVERED PHARMACEUTICALS**

The pharmaceuticals to which this Supplemental Rebate Agreement shall apply are the following:

Drug Name	NDC	Effective Date

**ATTACHMENT C  
REBATE FORMULA**

Drug Name	NDC	Guaranteed Net Unit Price
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State Supplemental Rebates shall be calculated according to the following formulae:

State Supplemental Rebate = (SRPU) x number of Units paid for by Maryland Medicaid during the Fiscal Quarter

State Supplemental Rebate Per Unit (SRPU) = (WAC- National Rebate per Unit – Guaranteed Net Unit Price